

8/5/2008 Telecon - Seraclone Blood Grouping Reagent Anti-S (Monoclonal)

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Date/Time: August 5, 2008 / 07:35 AM
CBER Representative: Najma Khan
Biotest' Representative: Ute Greiner
Subject: Discuss additional information required for submission.
To: Files of STNs listed below

Submission Tracking Numbers	Product Proper Names
BL 125202/0	Anti-E (Monoclonal) (Formulated for Automated Testing)
BL 125203/0	Anti-e (Monoclonal) (Formulated for Automated Testing)
BL 125204/0	Anti-K (Monoclonal) (Formulated for Automated Testing)
BL 125205/0	Anti-c (Monoclonal) (Formulated for Automated Testing)
BL 125206/0	Anti-C (Monoclonal) (Formulated for Automated Testing)
BL 125207/0	Reagent Red Blood Cells
BL 125208	Reagent Red Blood Cells (Formulated for Automated Testing)

Submission Tracking Numbers	Product Proper Names
BL 125212/0	Anti-Fy a (Monoclonal)
BL 125213/0	Blood Grouping Reagent, Anti-P 1 (Murine Monoclonal)
BL 125214/0	Anti-s (Monoclonal)
BL 125215/0	Anti-Human Globulin
BL 125216/0	Blood Grouping Reagent, Anti-S (Monoclonal)
BL 125217/0	Blood Grouping Reagent, Anti-Jkb (Monoclonal)
BL 125218/0	Anti-D (Monoclonal)(IgG Blend)(Formulated for Automated Testing)
BL 125219/0	Blood Grouping Reagent, Anti-A (Murine Monoclonal)
BL 125220/0	Blood Grouping Reagent, Anti-B (Murine Monoclonal)
BL 125221/0	Blood Grouping Reagent, Anti-A,B (Murine Monoclonal)
BL 125222/0	Blood Grouping Reagent, Anti-D (Monoclonal) (IgM)
BL 125223/0	Blood Grouping Reagent, Anti-D (Monoclonal Blend)
BL 125224/0	Blood Grouping Reagent, Anti-M (Murine Monoclonal)
BL 125225/0	Blood Grouping Reagent, Anti-N (Murine Monoclonal)
BL 125226/0	Blood Grouping Reagent, Anti-C (Monoclonal)
BL 125227/0	Blood Grouping Reagent, Anti-c ((Monoclonal)
BL 125228/0	Blood Grouping Reagent, Anti-E ((Monoclonal)
BL 125229/0	Blood Grouping Reagent, Anti-e ((Monoclonal)
BL 125230/0	Blood Grouping Reagent, Anti-K (Monoclonal)
BL 125231/0	Blood Grouping Reagent, Anti-Jka ((Monoclonal)
BL 125232/0	Blood Grouping Reagent, Anti-k (Murine Monoclonal)
BL 125233/0	Blood Grouping Reagent, Anti-Le a (Murine Monoclonal)
BL 125242/0	Anti-Human Globulin (Rabbit/Murine Monoclonal)
BL 125097/10	Blood Grouping Reagent, Anti-D (Monoclonal)(IgM)(Formulated for Automated Testing)
BL 125098/8	Anti-Human Globulin (Formulated for Automated Testing)

Introduction: Biotest AG applied for Biological License Applications (BLAs) for Blood Grouping Reagents, Reagent Red Blood Cells and Anti-Human Globulin.

Discussion: The question from FDA is in bold and italicized text is the response from the sponsor. The following one issue was discussed:

- 1. Please provide the following items for all biological products (STNs) that are pending for approval.**
 - a. Definition for the date of manufacture**
 - b. Dating period**
 - c. Product fill volume**

Biotest promised to fax the response within few hours.

Agreements/Decisions/Action:

- Biotest will fax the response.

Prepared by Najma Khan on August 5, 2008